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PCT/KR2004/002496

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference JL-22982-PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. **PCT/KR2004/002496**	International filing date *(day/month/year)* **25 SEPTEMBER 2004 (25.09.2004)**	Priority date *(day/month/year)* 29 SEPTEMBER 2003 (29.09.2003)

International Patent Classification (IPC) or national classification and IPC

IPC7 A61K 9/22

Applicant

CJ CORPORATION et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
28 APRIL 2005 (28.04.2005)	23 DECEMBER 2005 (23.12.2005)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM, Hee Sue Telephone No. 82-42-481-5605

Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2004/002496

Box No. I Basis of the report

1. With regard to the **language,** this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1(b))
   ☒ publication of the international application (under Rule 12.4)
   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this reort as "originally filed" and are not annexed to this report):*

   ☒ the international application as originally filed/furnished

   ☐ the description:
   pages _____ as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the claims:
   pages _____ as originally filed/furnished
   pages* _____ as amended (together with any statment) under Article 19
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the drawings:
   pages _____ as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets _____
   ☐ the sequence listing *(specify)* : _____
   ☐ any table(s) related to sequence listing *(specify)* : _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets _____
   ☐ the sequence listing *(specify)*: _____
   ☐ any table(s) related to sequence listing *(specify)* : _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2004/002496

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 9, 15, 16	YES
	Claims	1, 3-8, 10-14	NO
Inventive step (IS)	Claims		YES
	Claims	1-16	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present invention relates to a sustained-release formulation including: (a) a sustained-release core including an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions, (b) an enteric film coating layer coated on the sustained-release core, and (c) an active ingredient-containing film coating layer coated on the enteric film coating layer and comprising the active ingredient and a hydrophilic polymer.

The following documents have been considered for the purpose of this report:

D1 = WO 02-98352 A2 (12. 12. 2002)
D2 = WO 03-39531 A1 (15. 03. 2003)
D3 = WO 95-28148 A1 (26. 10. 1995)
D4 = US 5162117 (10. 11. 1992)
D5 = US 6106863 (22. 08. 2000)
D6 = US 5171580 (15. 12. 1992)
D7 = US 5425950 (20. 06. 1995)
D8 = WO 01-37812 A2 (31. 05. 2001)
D9 = US 5160742 (03. 11. 1992)

D1 discloses a controlled-release tablet of naproxen which comprises a core tablet of naproxen, an enteric coating and an outermost layer having an acid inhibitor.
D2 discloses a modified release tamsulosin tablet comprising a tablet matrix having dispersed tamsulosin and optionally an enteric coating over said matrix.
D3 discloses a tablet formulation comprising a core which includes a first active substance, the core being coated with a release retarding coating, the coated core being itself surrounded by a casing layer which includes a second active substance.
D4 discloses a controlled release flutamide tablet which comprises (a) a core having flutamide and a carrier, (b) an enteric coating material and (c) an immediate release outer coating layer having flutamide.
D5 discloses a sustained-release metal valproate tablet comprising a core tablet and double coating layers.
D6 discloses a pharmaceutical preparation for oral administration, which comprises a core comprising an active substance and multiple layer coating.

(Continued on Supplemental Sheet.)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Box V.

D7 discloses a controlled release pharmaceutical composition comprising: (a) an outer layer comprising a pH independent hydrophilic polymer together with one on more fillers; (b) an intermediate polymer layer (c) one or more inner layers each comprising an active ingredient dispersed throughout a polymer matrix.
D8 discloses a pharmaceutical gastroretentive drug delivery system for the controlled release of an active agent in the gastrointestinal tract, which system comprises: (a) a multi-layered matrix (a tablet, a capsule or a suitable two or three-dimensional matrix) comprising a polymer selected from a degradable polymer (a hydrophilic polymer, an enteric poymer, a hydrophobic polymer), a non-degradable polymer, (b) a continuous membrane comprising at least polymer having a substantial mechanical strength; and (c) a drug which is embedded in a layer of said matrix.
D9 discloses a drug delivery system which comprises (a) a core comprising an active substance in a matrix with excipients (b) a first coating on the core comprising one enteric compound and (c) a second coating overlying the first coat and comprising a prolamine.

1. Novelty
Claims 1, 3-8 and 10-14 of the present invention and the document D1 have the same object of providing a drug delivery system for the sustained-release of active substances to an environment of use. In addition, the present invention has the same technical composition as the invention of D1 in that D1 relates to the use of the enteric coating and the film coating containing an active substance on the surface of the tablet core as the sustained-release formulation. In addition, the documents D4, D6, D7 and D9 disclose the sustained-release drug dosage formulation. Therefore, said claims are considered to lack novelty over D1, D4, D6, D7 and D9.
The additional enteric coating on the film coating containing an active substance in claims 2 and 9 is different from the trilayer coating of D1. Tamsulosin used as the active substance in claims 15 and 16 is different from the active substance of D1. Therefore claims 2, 9, 15 and 16 are considered to be novel. [PCT Article 33(2)]

2. Inventive Step
However, there is no mention to confirm that the additional enteric coating has a surprisingly changed effect on the sustained-release of active substances. Further, the use of tamsulosin as an active substance is a simple change in materials which can be selected by a person skilled in the art, as shown in D2, and there is no remarkable difficulty in that. In addition, the resulting effect on the sustained-release rate of tamsulosin is expectable. Therefore, claims 2, 9, 15 and 16 are considered to lack an inventive step. [PCT Article 33(3)]

3. Industrial Applicability
The subject matter of claims 1-16 appears to be industrially applicable. [PCT Article 33(4)]